REMARKS

Office action summary. Claims 1-59 are rejected for failure to meet the written description requirement. Claims 1-59 are also rejected for lack of enablement.

These rejections are overcome by the amendments herein and otherwise traversed.

The Examiner's withdrawal of the rejection over 10/359,548 is much appreciated.

Claim amendments. Claim 1 is amended to eliminate a phrase which the Examiner found to lack written description. Claim 50 is amended to change "a moist environment" to the particular moist environment of relevance to the claimed method, the oral cavity. Support is found, for example, in paragraph [0042] noting that the oral cavity is one of the moist environments contemplated by the invention.

Enablement rejection. The Examiner's reasoning for maintaining the enablement rejection, despite the applicants' arguments, appears to be as follows (Office Action at 10-11):

> **[a]** The specification does not enable one skilled in the art to make erodible backing without undue experimentation because the materials used to make the backing materials do not having aqueous solubility as required by the claims. The polymers used for the backing member are disclosed as water-insoluble polymers, and used in the water-swellable, water-insoluble component of the hydrogel. **[b]** The erosion of these polymers, according to applicants' disclosure on paragraph 00114, are tailored by other ingredients and not only a property of the selected water-insoluble polymer. Therefore, undue experimentation becomes the burden of the skilled artisan to tailor the erosion of the water-insoluble polymers to achieve erosion of the backing member slower than the hydrogel in an aqueous environment as required by the claims. **[c]** Further, how the erosion of the backing member will be tailored if the different polymer is in the hydrogel?

Applicants endeavor to respond to the three points [a], [b], and [c] stated above.

As regards point [a], the Examiner seems to be concerned that certain classes of polymers disclosed in the specification as being usable in the erodible backing member are also described as "water-swellable, water-insoluble" polymers.[1] However, there is no contradiction there. The term "water-insoluble" is expressly defined in the specification as "refer[ring] to a compound or composition whose solubility in water is less than 5 wt%, preferably less than 3 wt%, more

1 The Examiner unfortunately does not give specific examples of the polymers that are of concern. However, the Examiner may be thinking of the statement in paragraph [00114] that "Preferred acrylate polymers are the Eudragit® copolymers .... As noted above, these Eudragit polymers also find utility as the water-swellable, water-insoluble polymer component of the hydrogel."

preferably less than 1 wt% (measured in water at 20°C)." (Application paragraph [0045].) An applicant is allowed to give special definitions to the terms used in the claims. See MPEP § 2111.01, part IV ("An applicant is entitled to be his or her own lexicographer . . . ."). Thus, a polymer can be "water-insoluble" in the sense of the claims and nonetheless have a nonzero aqueous solubility. In addition, as stated in paragraph [0037] of the specification, dissolution is not the only mechanism that can achieve erosion, and so there may be polymers which are described as insoluble but still erode.

As regards [b], the Examiner states that "the erosion of these polymers . . . are tailored by other ingredients and not only a property of the selected water-insoluble polymer." The Examiner seems to be thinking that the additional possible ways of achieving erodibility listed at the end of paragraph [00114] negate enablement. Paragraph [00114] says that "the grade used for the erodible backing can be selected to have a lower solubility as compared to the grade used in the hydrogel." This disclosure combined with the examples is sufficient to enable the person of skill in the art to find polymers for erodible backing members for hydrogels of practical interest. The fact that the applicants went on to suggest additional possibilities for tailoring erosion – "mixtures of Eudragit polymers or mixtures of Eudragit polymers with other polymers and excipients (e.g. buffering agents, pH modulators)" – does not mean that the enablement provided by the suggestion to use different grades of Eudragits is somehow negated.

As regards [c], the Examiner asks "how the erosion of the backing member will be tailored if the different polymer is in the hydrogel?" It is not completely clear what is meant here by "the different polymer." The hydrogel is one piece of the composition; the backing member is a separate piece. The hydrogel will erode at one rate, depending on what it is made of; the backing member at a different rate, determined by what the backing member is made of. The polymer in the hydrogel does not generally limit the designer's choice of polymer for the backing member. All that the designer has to do is find a polymer for the backing member that erodes more slowly than the hydrogel.

The Examiner may be imagining that there is some sort of compatibility problem, so that if the hydrogel is composed of particular polymers, then the backing member must be composed of other related polymers and Eudragits cannot be used. However, the Examiner has not given any reason why this compatibility problem would arise. The hydrogel and the backing member

are separate pieces of the composition claimed in claim 1. The polymers for the backing member can be chosen with considerable freedom, and are not in general limited by the polymers chosen for the hydrogel.

Examples. The Examiner has asserted that there is an absence of "working examples." (Office Action at 7.) However, applicants believe that the Examples 1-3 do in fact work, i.e., they are examples where the hydrogels erode more rapidly than the backing layers. In addition, the choices made in Examples 1-3 are in accordance with the more general guidance given in paragraph [00114] to choose different grades of Eudragit polymers. Thus, a person of skill in the art looking to practice the claims would have Examples 1-3 and could benefit from their teachings to immediately make compositions falling within the scope of the claims.

In addition, the patent incorporates by reference its ancestor U.S. Patent Application No. 10/137,664, cited in the first sentence (see general incorporation by reference statement in paragraph [00146]). The application has published as U.S. Patent Application No. 2003-0170308. That application provides a number of further examples of hydrogels comprising a blend of a hydrophilic polymer and a complementary oligomer. Those examples provide further enablement.[2]

In addition, the patent incorporates by reference its ancestor U.S. Patent Application No. 10/359,548, cited in the first sentence. That application has published as U.S. Patent Application No. 2003-0152528. That application provides further examples of hydrogels comprising a blend of a hydrophilic polymer and a complementary oligomer, used specifically for tooth whitening. Those examples provide further enablement. Note in particular the statement in Example 6 of this application that "Preliminary wear studies indicated that that Formulas A and B are capable of remaining on teeth for over 10-15 minutes . . . ." This provides further enablement for erosion rates of hydrogels.

Other *Wands* factors. In further support of the enablement of the claims, applicants add the following discussion of other *Wands* factors, as applied by the Examiner:

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2 The ancestor application in turn incorporates by reference copending U.S. Patent Application Serial No. 09/900,697, published as U.S. Patent Publication No. 2002-0037977, which provides still further examples of hydrogels comprising a blend of a hydrophilic polymer and a complementary oligomer and teaches how to optimize their adhesive properties.

(a) *The breadth of the claims.* Claim 1 recites "a blend of a hydrophilic polymer with a complementary oligomer capable of hydrogen or electrostatic bonding to the hydrophilic polymer." Hydrogels in which such a blend is the predominant component can be expected in general to have a relatively fast erodibility in moist environments due to the hydrolyzing of hydrogen bonds between the complementary oligomer and the hydrophilic polymer. Thus, finding a backing layer that erodes more slowly is not normally going to be a search that strains the existing knowledge of bioerodible polymers, which is extensive as discussed below.

(b) *The quantity of experimentation.* In connection with this *Wands* factor, the Examiner writes that "there is a substantial gap between a composition comprising a specific combination of hydrogel and backing member agents and one comprising any and all hydrogel and backing member agents. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap."[3] What the Examiner seems to be thinking is that enablement requires the person of skill in the art go through all possible combinations of polymers within the scope of the claim and test them, and thus the mere fact that a great many combinations could exist negates enablement. That is not, however, the law.

The quantity of experimentation is not the same thing as number of combinations encompassed by the claim. If it were, then it would be impossible for anyone to get broad composition claims to anything, simply because of the amount of work involved in making all the compositions within their scope. To make an analogy, in any claim that recites "a pharmaceutically acceptable carrier," it could be argued on the Examiner's reasoning that there is a lack of enablement because there are a great many pharmaceutically acceptable carriers known in the literature and, on the Examiner's view, "the amount of experimentation" includes that required to make them all. Given the existence of many claims in issued patents reciting a "pharmaceutically acceptable carrier" (29,234 in a recent search of the Office's public patent database), the Examiner's view cannot be the law.

Furthermore, there is no indication that the person of skill in the art would have any difficulty making and testing a great many combinations using the components suggested in the specification of the patent, if that person were so inclined. "[A] considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides

3 The Examiner also mentions this "gap" in connection with other *Wands* factors.

a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention." *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (internal quotation marks omitted). "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." MPEP § 2164.01.

(c) *The state of the prior art.* The Examiner does not discuss the *Wands* factor which is the state of the prior art (factor (C) in the list of *Wands* factors in MPEP § 2164.01(a)). The large literature on bioerodible and biodegradable polymers should also be taken into account in connection with this *Wands* factor. These polymers have been studied, for example, with respect to sustained release delivery in the gastrointestinal tract, where slow erosion has been used for years as a mechanism to achieve sustained release, with a number of polymers being studied for this purpose and extensive data being available on those polymers in the literature. An example of the extensive biodegradable polymer literature is *Biodegradable polymers as drug delivery systems* (Mark Chasin & Robert Langer eds., 1990). The literature in particular discusses, for example, lactide/glycolate polymers which exhibit very slow biodegradation on the order of months (see chapter 1 of preceding reference), as well as other polymers which degrade more rapidly. The extent of this literature weighs strongly in favor of enablement.

Enablement of dependent claims. As pointed out in the previous response, there are a number of narrower dependent claims. The Examiner has rejected all claims, both broad and narrow, for lack of enablement. There is no reasoning specific to the narrower claims.

In particular, there is no reasoning specific to claim 9, which limits the backing member to "polymers formed from acrylic acid, methacrylic acid, methyl acrylate, ethyl acrylate, methyl methacrylate, and ethyl methacrylate," i.e., the narrow class of polymers to which the Eudragits pertain and to which the examples and some statements in paragraph [00114] pertain. Even if the Examiner finds the guidance for backing members insufficient for backing members made out of any appropriate polymers, surely the guidance for the polymers recited in claim 9 is fully sufficient. Claim 15 is even more narrowly focused on the examples. If the Examiner continues to believe that the claims lack enablement, it would be most appreciated if the Examiner would provide reasoning specific to claims 9 and 15.

In addition, with respect to claim 50 and claims dependent on it, the claims are limited to tooth whitening and (with the current amendment) the relevant erosion rates are those occurring in the oral cavity and not in other possible moist environments. These limitations would further facilitate the task of the person of skill in the art in practicing the invention as recited in claims 50-59.

Written description rejection. It is believed that the written description rejection is overcome by the amendment to claim 1, which eliminates the phrase which the Examiner found objectionable. Applicants do not concede that the phrase in fact lacked written description.

Conclusion. It is hoped that the present response adequately explains why the Examiner's rejections are not well founded. If the Examiner has any questions about this response, it is respectfully requested that she telephone the undersigned attorney at his direct dial (650) 251-7712.

Respectfully submitted.

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